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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,228

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John A. Chiorini

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EXAMINER

BURKHART, MICHAEL D

ART UNIT

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1633

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,228	Applicant(s) CHIORINI ET AL.	
	Examiner Michael Burkhart	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19,41-46,64-69,91 and 102-111 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-19,41-46,64-69,91 and 102-111 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

***** Claims 109 and 110 are dependent upon cancelled claim 70. In order to further prosecution they have been restricted below as being dependent upon claim 68. Upon any amendment by applicants to correct claim dependency, claims 109 and 110 will be restricted accordingly. *****

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 - 9, drawn to a vector comprising a pair of BAAV ITRs and a promoter between, along with viral particles comprising the vector.

Group II, claim(s) 10 and 11, drawn to a BAAV particle containing a vector comprising a pair of ITRs from AAV1 - AAV8, AAV, or BAAV.

Group III, claim(s) 12 - 14, drawn to a nucleic acid comprising SEQ ID NO: 1 (what appears to be the BAAV genome).

Group IV, claim(s) 15 - 19, drawn to nucleic acids encoding the BAAV Rep proteins (Rep78 and Rep52).

Group V, claim(s) 41 and 42, drawn to a nucleic acid comprising the BAAV p5 promoter.

Group VI, claim(s) 43 and 44, drawn to a nucleic acid comprising the BAAV p19 promoter.

Group VII, claim(s) 45 and 46, drawn to a nucleic acid comprising the BAAV p40 promoter.

Group VIII, claim(s) 64 and 65, drawn to a nucleic acid comprising SEQ ID NO: 12 (what appears to be the BAAV ITR).

Group IX, claim(s) 66 - 68 (in part), 105 - 107, 109 and 110, drawn to a vector system comprising at least one vector comprising a nucleic acid selected from the group of: a pair of BAAV ITRs; encoding a BAAV capsid protein; or encoding a BAAV Rep protein: wherein two of the vectors are the BAAV Rep protein vector and the BAAV ITR vector.

Group X, claim(s) 66 - 67 (in part), 69, 102, 105 - 108 drawn to a vector system comprising at least one vector comprising a nucleic acid selected from the group of: a pair of BAAV ITRs; encoding a BAAV capsid protein; or encoding a BAAV Rep protein: wherein one of the vectors encodes both the Rep and Cap proteins, and the second vector comprises the BAAV ITR's; or all of the above components are found on a single vector.

Group XI, claim(s) 66 - 67 (in part), 91, 103 - 107 and 111 drawn to a vector system comprising at least one vector comprising a nucleic acid selected from the group of: a pair of BAAV ITRs; encoding a BAAV capsid protein; or encoding a BAAV Rep protein: wherein one of the vectors encodes the capsid protein, and the second vector comprises the BAAV ITR's.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Many of the independent claims (e.g. claims 1, 10, 15, 41, etc.) recite broad terms such as "BAAV inverted terminal repeat", "BAAV Rep protein", "BAAV p5 promoter", etc. The specification indicates that the scope of these terms is to include molecules with as little as 70%

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homology (see e.g. pages 19 and 20 of the instant specification. Thus, because it is the amino acid or nucleic acid sequence that provides the structural basis for the claimed molecules, and is used to define such molecules over the prior art, it is considered that prior art molecules within the homology range set forth in the specification are considered to meet the broad scope of the instant claims.

The technical feature linking Groups I and II is a vector comprising a pair of BAAV ITR's and a promoter. Although not specifically recited in the independent claim 10, a promoter is implied in claim 11. This reasoning also applies for Groups IX - XI, which recite vectors comprising BAAV ITR's but do not specifically recite a promoter until dependent claims 103 and 104. Hildinger et al (WO 01/83692, cited in the search report and written opinion of the instant application, issued as U.S. 7,056,502) disclose AAV5 vectors comprising a pair of ITR's with 95% identity to the instantly disclosed BAAV ITR (i.e. SEQ ID NO: 12), along with, *inter alia*, a transgene comprising a promoter. See, in particular, cols. 2 - 3, 5 - 6 and 8 of the '502 patent.

The technical feature linking Groups IV and IX - XI is a nucleic acid encoding a BAAV Rep protein. Chiorini et al (WO 01/70276, cited in the search report and written opinion of the instant application, issued as U.S. 6,855,314) disclose AAV5 Rep proteins having 90% (Rep 78) or 87% (Rep 52) identity to the instantly disclosed BAAV Rep proteins, and thus are considered to be within the scope of the broad recitation of a "BAAV Rep protein" as found in each of the above groups for reasons set forth above.

The technical feature linking Groups I and V is a nucleic acid encoding a BAAV p5 promoter. Chiorini et al (as above) disclose an AAV5 p5 promoter having 90% identity to the instantly disclosed BAAV p5 promoter, and thus is considered to be within the scope of the broad recitation of a "BAAV p5 promoter" as found in each of the above groups for reasons set forth above.

The technical feature linking Groups IX and XI is any one of the nucleic acid vectors as recited, for example, in claim 66, which only requires one of the vectors. Such vectors comprising BAAV ITRs and the BAAV Rep proteins are disclosed by either Chiorini et al or Hildinger et al for the reasons set forth above.

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Therefore, the technical features linking the inventions of Groups I and II; Groups IV and IX - XI; Groups I and V; and Groups IX and XI do not constitute special technical features as defined by PCT Rule 13.2, as they not define a contribution over the prior art.

The technical feature of Group I is considered to be a vector comprising a pair of BAAV ITRs and a promoter between, a technical feature not found in Groups III - XI.

The technical feature of Group II is considered to be a BAAV particle containing a vector comprising a pair of ITRs from AAV1 - AAV8, AAV, or BAAV. This technical feature is not found in any of the other Groups, save the BAAV particle of Group I.

The special technical feature of Group III is considered to be a nucleic acid comprising SEQ ID NO: 1. This special technical feature is not found in any of the other Groups.

The technical feature of Group IV is considered to be nucleic acids encoding the BAAV Rep proteins (Rep78 and Rep52). This technical feature is not found in Groups I-III, V-VIII, and only partially in Groups IX-XI.

The technical feature of Group V is considered to be a nucleic acid comprising the BAAV p5 promoter. This technical feature is not found in Groups II-IV, and VI -XI.

The technical feature of Group VI is considered to be a nucleic acid comprising the BAAV p19 promoter. This technical feature is not found in any of the other Groups.

The technical feature of Group VII is considered to be a nucleic acid comprising the BAAV p40 promoter. This technical feature is not found in any of the other Groups.

The special technical feature of Group VIII is considered to be a nucleic acid comprising SEQ ID NO: 12. This special technical feature is not found in any of the other Groups.

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The technical feature of Group IX is considered to be a vector system wherein two of the vectors are the BAAV Rep protein vector and the BAAV ITR vector. This technical feature is not found in any of the other Groups.

The technical feature of Group X is considered to be a vector system wherein one of the vectors encodes both the Rep and Cap proteins, and the second vector comprises the BAAV ITR's. This technical feature is not found in any of the other Groups.

The technical feature of Group XI is considered to be a vector system wherein one of the vectors encodes the BAAV capsid protein, and the second vector comprises the BAAV ITR's. This technical feature is not found in any of the other Groups.

Accordingly, Groups I-XI are not so linked by the same concept or a corresponding technical feature as to form a single general inventive concept.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species Election I, in Group I, choose one of the types of recombinant parvovirus particles as recited in claims 6 and 7, and identify whether or not the selection is within the scope of claims 8 or 9;

Species Election II, in Groups IX - XI, choose one of the types of AAV particles as recited in claim 107, and identify whether or not the selection is within the scope of claims 105 or 106.

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Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: for Species Election I, claims 1-4, for example, are generic. For Species Election II, claims 66 and 67, for example, are generic.

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF INVENTIONS

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is

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provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Burkhart whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhart/
Primary Examiner, Art Unit 1633